REMARKS

The present invention provides a method for cleaning and disinfecting biomaterials that have the ability to reversibly sorb cationic antimicrobial agents. Such biomaterials appear to accumulate antimicrobial agents when they are in contact with a solution having an antimicrobial concentration sufficient to drive sorption of the antimicrobial agents to the biomaterials. Upon such biomaterial contact with an aqueous solution having lower antimicrobial concentrations, the antimicrobial agents are desorbed. In the case of contact lenses, over a period of time the positively charged, ionically bound antimicrobial agents are released from the biomaterial forming the lens through displacement by endogenic ions in the tear film and can cause tissue irritation.

The method of the present invention inhibits the ability of a biomaterial to sorb cationic antimicrobial agents. The subject method comprises treating the surface of an anionic hydrogel biomaterial with a cationic polysaccharide.

Claims 1, 3, 5-6, 9-11, 14-17 and 23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ellis et al., U.S. Patent Number 5,401,327.

Applicants respectfully traverse the subject rejection of claims 1, 3, 5-6, 9-11, 14-17 and 23 under 35 U.S.C. 102(b). Ellis et al., '327 discloses the use of an ophthalmic solution including polyethylene oxide (PEO) components composed of a hydrophobic core having at least three carbon atoms and at least three hydrophilic polyethylene oxide chains attached to the core. The core of these "star-like" components provides a means, when adsorbed on a surface, to achieve a high, localized density of PEO chains across the surface to increase the hydrophilicity thereof and thereby provide protein resistance.

To the contrary, claims 1, 3, 5-6, 9-11 and 14-17 of the present application provide a method for inhibiting the **ability of a hydrogel biomaterial to sorb** cationic antimicrobial agents through the use of simple cationic polysaccharides. The subject method as disclosed and claimed differs significantly from the method disclosed by Ellis et al., '327 relating to "star-like" components for treating lenses to repel protein deposits from forming on the surface of treated lenses. It is the position of the Office that "treatment of similar surfaces with similar materials would inherently yield the same results". To the contrary, the material of the present invention is not the same or similar to the star-like component containing material of Ellis. Hence, the unique method of the present invention for inhibiting the ability of a biomaterial to sorb cationic antimicrobials as disclosed and claimed differs significantly from the patented invention described by Ellis et al., '327. For this reason in addition to others not set forth herein, the rejection of claims 1, 3, 5-6, 9-11 and 14-17 under 35 U.S.C. 102(b) is inappropriate. Withdrawal of the rejection of claims 1, 3, 5-6, 9-11 and 14-17 under 35 U.S.C. 102(b) is respectfully requested.

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Claims 1-7, 9-16 and 19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ellis et al., U.S. Patent Number 4,321,261.

Applicants respectfully traverse the subject rejection of claims 1-7, 9-16 and 19 under 35 U.S.C. 102(b). Ellis et al., '261 discloses a contact lens solution for wetting, soaking and lubricating hard contact lenses. The lens solution includes an ionic polymer of **cationic or anionic charge**, preservatives, viscosity modifiers, lubricity agents, soaking and cleaning agents and buffers. The ionic polymer in the solution serves to interact with an oppositely charged lens surface to form a polyelectrolyte complex. The polyelectrolyte complex has an equal amount of cations and anions. The electrically neutral complex exists as an ionically cross-linked hydrogel that is effective in retaining water of hydration (Col.3, lines 5-9).

To the contrary, claims 1-7, 9-16 and 19 of the present application provide a method for inhibiting the ability of a biomaterial to **sorb (I ns internal polymer matrix)** cationic antimicrobials through the use of cationic polysaccharides. The subject method as disclosed and claimed differs significantly from the description of Ellis et al., '261 relating to methods for inhibiting protein **adhesion (lens external polymer matrix)** to the surface of a contact lens through the use of anionic or cationic polymers. Accordingly, the unique method of the present invention that unexpectedly inhibits the ability of a biomaterial to sorb cationic antimicrobial agents as disclosed and claimed differs significantly from the patented invention described by Ellis et al., '261. It is unexpected that the subject method would be effective in inhibiting the ability of a biomaterial to sorb cationic antimicrobial agents since an electrical bilayer exists. Negative ions beneath the cationic polysaccharides could serve as a bridge to transport cationic antimicrobials and allow the same to sorb into the biomaterial. Unexpectedly, this is not the case. For these reasons in addition to others not set forth herein, the rejection of claims 1-7, 9-16 and 19 under 35 U.S.C. 102(b) is inappropriate. Withdrawal of the rejection of claims 1-7, 9-16 and 19 under 35 U.S.C. 102(b) is respectfully requested.

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Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al., '327 or Ellis et al., '261.

Applicants respectfully traverse the subject rejection of claim 18 under 35 U.S.C. 103(a). Ellis et al., '327 teaches "star-like" components for treating lenses to repel protein deposits as described in more detail above.

Ellis et al., '261 teach the use of ionic (anionic or cationic) polymers to form ionically cross-linked hydrogels that are effective in retaining water of hydration as described in more detail above.

To the contrary, claim18 of the present application provides a method for inhibiting the **ability of a biomaterial to sorb** cationic antimicrobials. Such is unique regardless of the end use of the biomaterial whether it be an extended wear contact lens or any other medical device. The subject method as disclosed and claimed differs significantly from the teachings and suggestions of Ellis et al., '327 or Ellis et al., '261. Methods suitable for repelling proteins from the surface of a lens are not necessarily suitable for inhibiting sorption of cationic antimicrobials into the interior matrix of a biomaterial. Likewise, methods suitable for forming ionically cross-linked hydrogels that are effective in retaining water of hydration are not necessarily suitable for inhibiting sorption of cationic antimicrobials into the interior matrix of a biomaterial. Accordingly, the subject invention is neither taught nor suggested by the unrelated methods of Ellis et al. '327 or Ellis et al. '261. Accordingly, the unique method of the present invention for inhibiting the ability of a biomaterial to sorb cationic antimicrobials as disclosed and claimed is not obvious in view thereof. For these reasons in addition to others not set forth herein, the rejection of claim 18 under 35 U.S.C. 103(a) is inappropriate. Withdrawal of the rejection of claim18 under 35 U.S.C. 103(a) is respectfully requested.

Pending claims 1-7, 9-19 and 23 as written are believed to be patentable. Allowance of pending claims 1-7, 9-19 and 23 is thereby respectfully requested.

Should there be any questions regarding this communication, please feel free to contact the undersigned at (636) 226-3340.

Respectfully submitted,

Rita D. Vacca
Reg. No.: 33,624

Bausch & Lomb, Inc.
One Bausch & Lomb Place
Rochester, New York 14604-2701